

A2
5. (Amended) A pharmaceutical composition according to claim 1, which comprises from about 0.5% to 30% by weight of carboxyvinyl polymer to provide drug release over a period of from about 8 hours to about 24 hours.

A3
12. (Amended) A sustained release tablet comprising bupropion hydrochloride and carboxyvinyl polymer and lactose, wherein the tablet is substantially free of an acidic pharmaceutical carrier as a stabilizer.

13. (Amended) A sustained release tablet comprising bupropion hydrochloride and carboxyvinyl polymer and microcrystalline cellulose, wherein the tablet is substantially free of an acidic pharmaceutical carrier as a stabilizer.

REMARKS

Claims 1-17 are pending in the present application.

Claim 6 has been objected to as being in improper dependent form. Claim 5 has been amended to recite an amount of carboxyvinyl polymer that is greater than that recited in claim 6. Support for the amendment may be found at page 4, lines 16-17. Accordingly, the objection of claim 6 has been addressed.

The Examiner has rejected claims 1, 3, 4 and 10-13 under 35 U.S.C. 102(a) as being anticipated by Apelian et al. (U.S. Patent 6,153,223, "Apelian"). Apelian is directed to a stabilized pharmaceutical composition comprising a pharmaceutical agent such as bupropion HCl and a stabilizing amount of an acidic pharmaceutically acceptable carrier to stabilize the pharmaceutical agent. Apelian teaches that the acidic pharmaceutically acceptable carrier is a dried premixture of a pharmaceutically acceptable carrier and an aqueous solution of an acid (col. 4, line 62 to col. 5, line 2). Pharmaceutically acceptable carrier include microcrystalline cellulose, powdered cellulose, lactose, and starch (col. 6, lines 13-18). Aqueous solution of an acid include hydrochloric acid, nitric acid, sulfuric acid, and phosphoric acid (col. 6, lines 39-46).

The teaching of Apelian is different from the presently claimed pharmaceutical composition comprising bupropion HCl and carboxyvinyl polymer in an effective stabilizing amount. Claim 1, as amended, specifically recite that the pharmaceutical composition is substantially free of acidic pharmaceutical acceptable carrier. Since the present invention does not

employ an acidic pharmaceutically acceptable carrier as a stabilizer of bupropion HCl, adding a limitation to claim 1 that the pharmaceutical composition is "substantially free of an acidic pharmaceutical carrier as a stabilizer" distinguishes the present invention from Apelian.

Further, the Examiner notes that Apelian discloses that 98.9% of the original agent was present (Example F) after 3 months of storage at 40 degrees Celsius and 75% humidity. The Examiner, therefore, concludes that this disclosure renders the claims of the present invention anticipated. We believe this statement is incorrect because this stability data is for the composition comprising bupropion HCl and an acidic pharmaceutical acceptable carrier (dilute hydrochloric acid), which composition does not comprise any carboxyvinyl polymer. Therefore, this stability data should not be used against a different composition as claimed in the present application.

The rejection to claims 3, 4, 10 and 11, which are dependent claims of claim 1, can be overcome for the same reasons. Claims 12 and 13 have been amended to add the same limitation as claim 1. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 4 and 10-13 under 35 U.S.C. 102(a) as being anticipated by Apelian be withdrawn.

The Examiner further rejected claims 1-17 of the present invention as obvious under 35 U.S.C. 103(a) over Apelian et al. in view of Seth (U.S. Patent 6,033,686). Seth discloses a sustained release tablet comprising bupropion HCl, and a water insoluble, water-permeable film-forming polymer. Therefore, the Examiner concludes that a skilled artisan would have been motivated to follow the suggestions of Seth to use a water soluble polymer in combination with bupropion HCl in order to impart the specific release profile of Seth to the formulation of Apelian.

As discussed above, Apelian does not teach a pharmaceutical composition comprising bupropion HCl and carboxyvinyl polymer in an effective stabilizing amount that is substantially free of an acidic pharmaceutical carrier as a stabilizer. Seth also does not suggest or teach such a pharmaceutical composition.

Accordingly, the combination of Apelian and Seth cannot teach the claimed pharmaceutical composition that is substantially free of any acid pharmaceutical carrier as a stabilizer. It is respectfully requested that the rejection of claims 1-17 as obvious under 35 U.S.C. 103(a) over Apelian et al. in view of Seth be withdrawn.

It is respectfully submitted that all the pending claims are now in a condition for allowance, notice of which is earnest solicited.

Respectfully submitted,
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AMENDMENTS TO THE CLAIMS SHOWING CHANGES

IN THE CLAIMS:

1. (Amended) A pharmaceutical composition in solid form comprising bupropion hydrochloride and carboxyvinyl polymer in an effective stabilizing amount, wherein the composition is substantially free of an acidic pharmaceutical carrier as a stabilizer.

5. (Amended) A pharmaceutical composition according to claim 1, which comprises from about [5%] 0.5% to 30% by weight of carboxyvinyl polymer to provide drug release over a period of from about 8 hours to about 24 hours.

12. (Amended) A sustained release tablet comprising bupropion hydrochloride and carboxyvinyl polymer and lactose, wherein the tablet is substantially free of an acidic pharmaceutical carrier as a stabilizer.

13. (Amended) A sustained release tablet comprising bupropion hydrochloride and carboxyvinyl polymer and microcrystalline cellulose, wherein the tablet is substantially free of an acidic pharmaceutical carrier as a stabilizer.